



U.S. Department
of Transportation

Pipeline and
Hazardous Materials
Safety Administration

COMPETENT AUTHORITY CERTIFICATION
FOR A TYPE B(U)

RADIOACTIVE MATERIALS PACKAGE DESIGN
CERTIFICATE USA/0596/B(U)-96, REVISION 3

East Building, PHH-23
1200 New Jersey Avenue Southeast
Washington, D.C. 20590

REVALIDATION OF UNITED KINGDOM COMPETENT AUTHORITY
CERTIFICATE GB/3605D/B(U)-96

This certifies that the radioactive material package design described is hereby approved for use within the United States for import and export shipments only. Shipments must be made in accordance with the applicable regulations of the International Atomic Energy Agency¹ and the United States of America².

1. Package Identification - U. K. Design No. 3605D.
2. Package Description and Authorized Radioactive Contents - as described in United Kingdom Certificate of Competent Authority GB/3605D/B(U)-96, Issue 4 (attached).
3. General Conditions -
 - a. Each user of this certificate must have in his possession a copy of this certificate and all documents necessary to properly prepare the package for transportation. The user shall prepare the package for shipment in accordance with the documentation and applicable regulations.
 - b. Each user of this certificate, other than the original petitioner, shall register his identity in writing to the Office of Hazardous Materials Technology, (PHH-23), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington D.C. 20590-0001.
 - c. This certificate does not relieve any consignor or carrier from compliance with any requirement of the Government of any country through or into which the package is to be transported.

¹ "Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), No. TS-R-1 (ST-1, Revised)," published by the International Atomic Energy Agency(IAEA), Vienna, Austria.

² Title 49, Code of Federal Regulations, Parts 100-199, United States of America.

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- d. Records of Quality Assurance activities required by Paragraph 310 of the IAEA regulations¹ shall be maintained and made available to the authorized officials for at least three years after the last shipment authorized by this certificate. Consignors in the United States exporting shipments under this certificate shall satisfy the applicable requirements of Subpart H of 10 CFR 71.
4. Marking and Labeling - The package shall bear the marking USA/0596/B(U)-96 in addition to other required markings and labeling.
5. Expiration Date - This certificate expires on March 31, 2012.

This certificate is issued in accordance with paragraph 808 of the IAEA Regulations and Section 173.473 of Title 49 of the Code of Federal Regulations, in response to the May 04, 2007 petition by GE Healthcare, Arlington Heights, IL, and in consideration of other information on file in this Office.

Certified By:



Bob Richard
Deputy Associate Administrator for Hazardous Materials Safety

May 18 2007
(DATE)

Revision 3 - Issued to revalidate U. K. Certificate of Approval of Package Design GB/3605D/B(U)-96, Issue 4, which corrected an error in Issue 3.



Certificate of Approval of Package Design for the Carriage of Radioactive Materials

THIS IS TO CERTIFY that the Secretary of State for Transport being, for the purposes of the Regulations of the International Atomic Energy Agency, the Competent Authority of Great Britain in respect of inland surface transport and of the United Kingdom of Great Britain and Northern Ireland in respect of sea and air transport and the Department of the Environment for Northern Ireland being the Competent Authority of Northern Ireland in respect of inland surface transport, have approved the Package design as specified in section 1 of this certificate, as applied for by GE Healthcare Ltd (see section 6).

as Type B(U)

by road, rail, sea and air

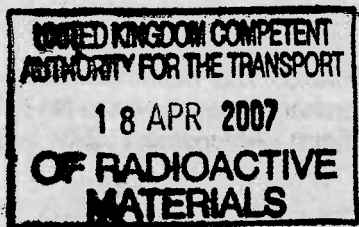
Packaging identification: 3605D

Packages manufactured to this design meet the requirements of the regulations and codes on page 2, relevant to the mode of transport, subject to the following general condition and to the conditions in the succeeding pages of this certificate.

In the event of any alteration in the composition of the package, the package design, the quality assurance programme(s) associated with the package or in any of the facts stated in the application for approval, this certificate will cease to have effect unless the Competent Authority is notified of the alteration and the Competent Authority confirms the certificate notwithstanding the alteration.

Expiry Date: This certificate is valid until the end of March 2012

COMPETENT AUTHORITY IDENTIFICATION MARK: GB/3605D/B(U)-96



PP

Transport Radiological Adviser
Department for Transport
Great Minster House
76 Marsham Street
London SW1P 4DR

*On behalf of the Secretary of State for Transport,
and the Department of the Environment for Northern Ireland*

This certificate does not relieve the consignor from compliance with any requirement of the government of any country through or into which the package will be transported.

REGULATIONS AND CODES OF PRACTICE GOVERNING THE TRANSPORT OF RADIOACTIVE MATERIALS

INTERNATIONAL

International Atomic Energy Agency (IAEA)

TS-R-1 Regulations for the Safe Transport of Radioactive Materials 1996 Edition (Revised) or 1996 Edition (As Amended 2003).

International Maritime Organisation (IMO)

International Maritime Dangerous Goods (IMDG) Code (Amdt 32-04).

International Civil Aviation Organisation (ICAO)

Technical Instructions for the Safe Transport of Dangerous Goods by Air 2005-2006 Edition.

United Nations Economic Commission for Europe (UNECE)

European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) 2005 Edition.

Intergovernmental Organisation for International Carriage by Rail (OTIF)

Convention concerning International Carriage by Rail (COTIF) Appendix B. Uniform Rules concerning the Contract for International Carriage of Goods by Rail (CIM) Annex 1 Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) 2005 Edition.

UNITED KINGDOM

ROAD

GREAT BRITAIN ONLY.

The Radioactive Material (Road Transport) (Definition of Radioactive Material) Order 2002, SI 2002 No. 1092.

The Radioactive Material (Road Transport) Regulations 2002, SI 2002 No. 1093.

The Radioactive Material (Road Transport) (Amendment) Regulations 2003 SI 2003 No 1867.

NORTHERN IRELAND ONLY.

The Radioactive Substances (Carriage by Road) Regulations (Northern Ireland) 1983, SR 1983 No 344. The

Radioactive Substances (Carriage by Road) (Amendment) Regulations (Northern Ireland) 1986, SR 1986 No 61.

RAIL

GREAT BRITAIN ONLY.

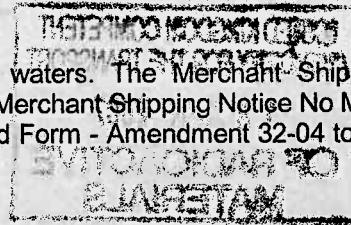
The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2004, SI 2004 No 568. The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations 2005, SI 2005 No 1732.

SEA

British registered ships. All other ships whilst in United Kingdom territorial waters. The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997, SI 1997 No 2367; Merchant Shipping Notice No MSN 1791(M), "The Carriage of Dangerous Goods and Marine Pollutants in Packaged Form - Amendment 32-04 to the International Maritime Dangerous Goods (IMDG) Code".

AIR

The Air Navigation Order 2005, SI 2005 No 1970. The Air Navigation (Dangerous Goods) Regulations 2002, SI 2002 No 2786. The Air Navigation (Dangerous Goods) (Amendment) Regulations 2004, SI 2004 No 3214.



1. PACKAGE DESIGN SPECIFICATION

The Package Design Specification shall be in accordance with GE Healthcare Ltd Safety Report reference TAD 3605D issue 11 dated 9 March 2007 and modifications to the package design approved by the authority named on page 1 of this certificate under the established modifications procedure.

1.1 Specification of Packaging

Design No.	Title / No. of Components	Drawing List	Issue
3605	Outer / Steel Drum with Cork Spacers / One	DL 25180 and PGM 865	J
3055 (C)	Intermediate / Stainless Steel Pot / One	DL22310	7 O
0035 (Mk 3) or 0035 (Mk 4) or 0035 (Mk 5)	Inner / Tritium Pots / One	DL23205 DL23549 DL27816	F G B

[(C) = Containment System]]

1.2 Permitted Contents

Tritium gas adsorbed on pyrophoric uranium in a stainless steel vessel.

1.3 Restrictions on Contents

The maximum activity of the permitted contents may be up to 4 PBq of tritium and 6 MBq of depleted uranium.

1.3 Package Dimensions and Weights

- Nominal Dimensions: 325mm diameter x 405mm high (see section 5 for package illustration)
- Maximum authorised gross weight: 20.7 kg

2. USE OF PACKAGE

2.1 Use of packaging

- The packaging shall be used, handled and maintained in accordance with the requirements of GB.PQ.146.E Version 4 dated 28 June 2006.

2.2 Actions prior to shipment

- a) Administrative controls shall ensure that the contents are in accordance with section 1 of this certificate, and that the consignor and consignee hold a copy of the instructions on the use of the packaging.
- b) The package is not required to reach thermal equilibrium prior to shipment.

2.3 Emergency Arrangements

a) Road, Rail and Ports in GB

(i) RADSAFE member

In the event of an emergency the procedures set out in RADSAFE (the nuclear industry transport emergency plan) shall apply. The police shall be informed that RADSAFE has been initiated.

(ii) Non RADSAFE member

Before shipment takes place, the consignor shall have drawn up suitable emergency plans, copies of which shall be supplied to the UK Competent Authority on demand. In the event of an emergency these emergency plans shall be initiated and the police informed.

b) Sea

In the event of an emergency, the procedure set out in the IMDG Code as quoted on page 2 of this certificate shall apply.

- c) If RADSAFE, the consignor's own, or other approved emergency plans cannot be initiated, for any reason, then the police shall be informed immediately and requested to call the local NAIR (National Arrangements for Incidents involving Radioactivity) establishment.

3. QUALITY ASSURANCE

3.1 Quality assurance programmes applicable to this design are:

- a) GE Healthcare Ltd Transport Safety Arrangements and
- b) any other quality assurance programmes associated with the design, manufacture, testing, documentation, use, maintenance and inspection, and for transport and in-transit storage operations, which must also comply with national or international standards for quality assurance which are acceptable to the authority named on page 1 of this certificate.

- 3.2 No alterations shall be made to the quality assurance programmes associated with this design and approved by the authority named on page 1 of this certificate unless that alteration has the prior approval of said authority, or it falls within the agreed change control procedures of that programme.
- 3.3 No quality assurance programme shall be used at any stage of the design, manufacture, testing, documentation, use, maintenance and inspection, and for transport and in-transit storage operations, unless said programme forms part of or is the quality assurance programme approved by the authority named on page 1 of this approval certificate.
- 3.4 During the conversion process from the previously approved 0666AY package to this 3605D design, using the inspection procedure GB.PQ.126.E Version 1, the serial numbers or batch numbers of the previously used components must be recorded and related to any new serial numbers assigned in order to maintain traceability to original manufacture records.

4. ADMINISTRATIVE INFORMATION

4.1 Other related certificates (alternative radioactive contents)

- a) This certificate forms the base approval of this design. Other related UK certificates using the 3605 outer are shown below: -

Certificate Reference & Issue	Certificate Type	Expiry Date
GB/3605C/B(U)-96 Issue 2	Design	30 September 2007
GB/3605M/B(U)-96 Issue 1	Design	30 November 2008

The list in 4.1(a) was complete at the time of compilation of this design approval certificate. Other related certificates may exist.

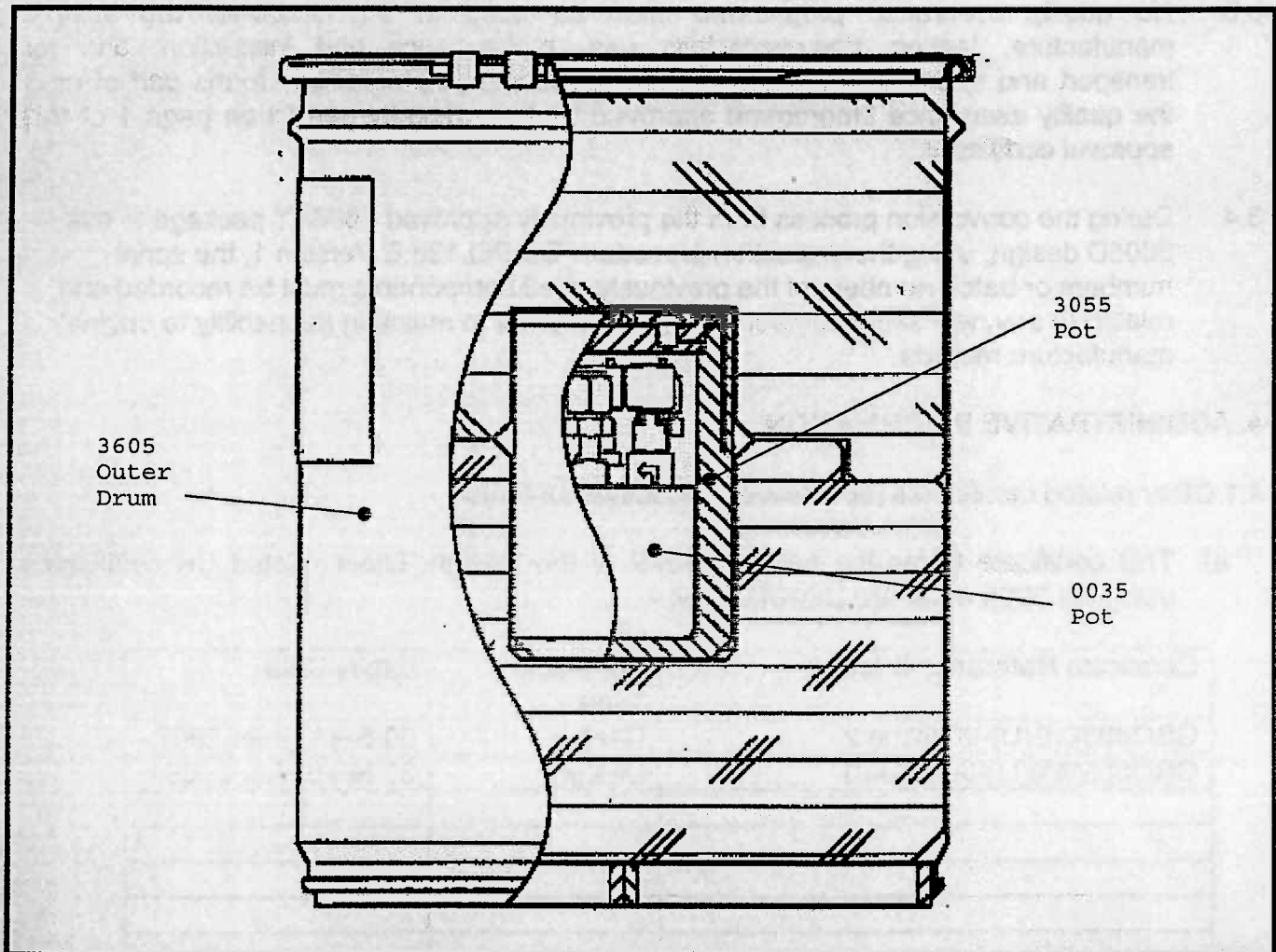
4.2 Additional Technical Data / Information

At the time of compilation of this design approval certificate, The Ionising Radiations Regulations 1999, SI 1999 No 3232 and Approved Code of Practice apply, with regard to radiation protection, to all modes of transport and The Dangerous Substances in Harbour Areas Regulations 1987, SI 1987 No 37, apply in UK Ports

4.3 Renewal of Certificates

- a) If the period of validity is required to be extended, application shall be made at least one year in advance of expiry.

5. PACKAGE ILLUSTRATION



6. CERTIFICATE STATUS

Design Approval issued to:-
GE Healthcare Ltd
The Grove Centre
Amersham
Buckinghamshire HP7 9NA

Issue No.	Date of Issue	Date of Expiry	Reason for Revision
GB/3605D/B(U)-96 Issue 1	25 September 2005	End of September 2006	First issued under new regulations
GB/3605D/B(U)-96 Issue 2	25 September 2005	End of September 2006 Extended by letter to 31 April 2007	Minor typographical changes.
GB/3605D/B(U)-96 Issue 3	23 March 2007	31 March 2012	Renewal on expiry of an extension to the previous certificate.
GB/3605D/B(U)-96 Issue 4	As date stamp on first page	31 March 2012	Issued to correct an error in section 2.1 a) of the issue 3 certificate.



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Washington, D.C. 20590

CERTIFICATE NUMBER: USA/0596/B(U)-96, Revision 3

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